

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER AT EL PASO
D19-01056

Animal Welfare Assurance for Domestic Institutions

I, Deborah Clegg, PhD as named Institutional Official for animal care and use at Texas Tech University Health Sciences Center at El Paso (TTUHSC El Paso), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the Public Health Service (PHS), Health and Human Service (HHS), National Science Foundation (NSF) and/or National Aeronautics and Space Administration (NASA). This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

TTUHSC El Paso

L. Frederick Francis Graduate School of Biomedical Sciences

Paul L. Foster School of Medicine

Gayle Greve Hunt School of Nursing

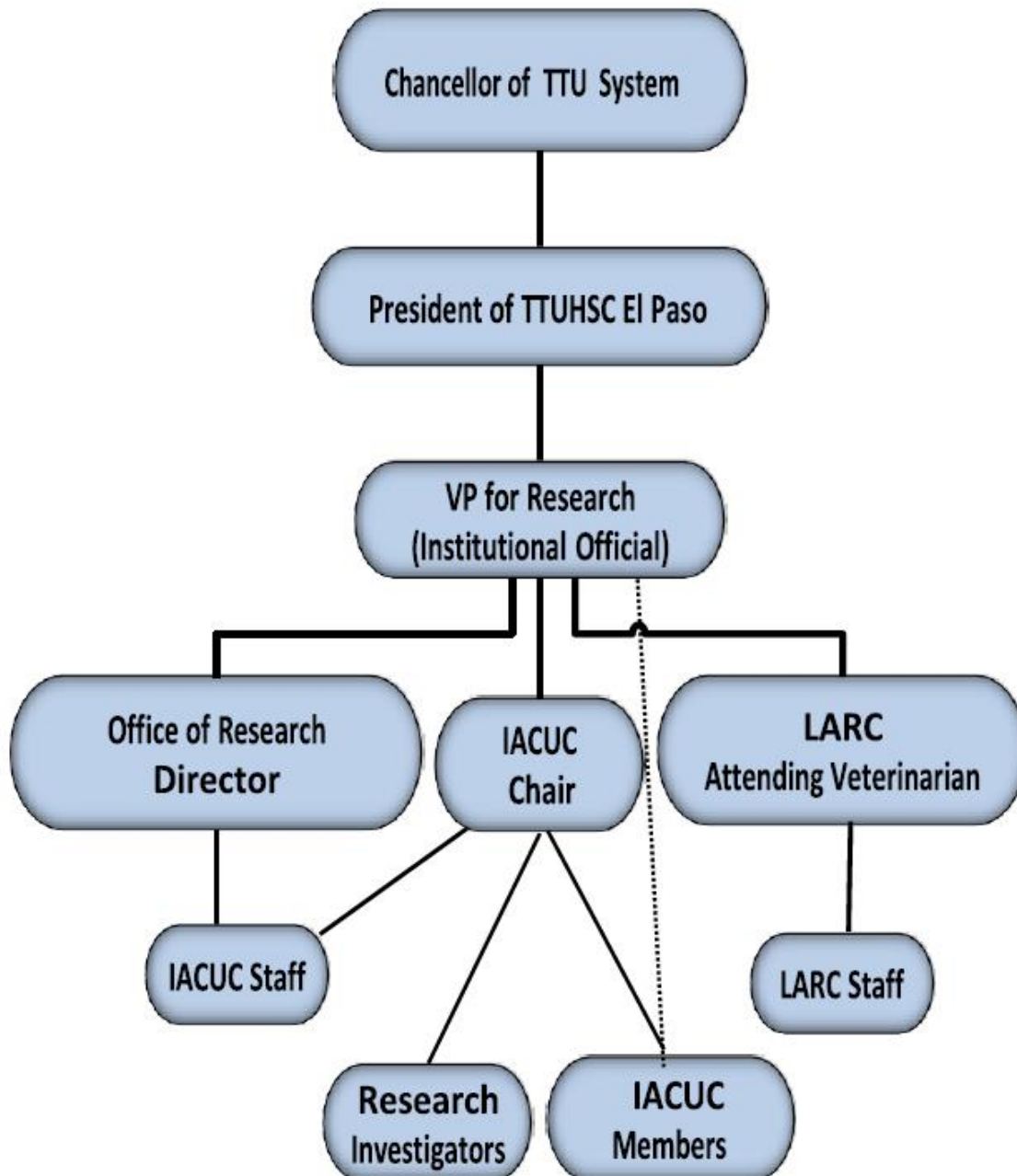
Woody L. Hunt School of Dental Medicine

- B. The following are other institution(s), or branches and components of another institution:
None

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use



- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:
- 1) **Name:** Violeta Salais, DVM-Institutional/Attending Veterinarian
Qualifications

- **Degrees:** DVM, 2018, Ross University School of Veterinary Medicine
- **Training or experience in laboratory animal medicine or in the use of the species at the institution:** Dr. Salais earned her DVM from Ross University School of Veterinary Medicine in 2018. She completed a clinical year at Oklahoma State University in 2017-2018. She worked as the Attending Veterinarian at the University of Texas at El Paso, at Paws N Hooves Mobile Veterinary Services & Mesa Veterinary Clinic as an Associate DVM, and at other locations in different capacities. Dr. Salais is the Institutional/Attending Veterinarian (IVET) for the El Paso Laboratory Animal Resource Center (LARC).

Authority: Dr. Salais has direct program authority and responsibility for the institution's animal care and use program including access to all animals.

Time contributed to program: Full Time 100%

2) **Name:** Pratish J. Parbhoo, DVM-Backup Veterinarian
Qualifications

- **Degrees:** DVM, 2012, Texas A&M University
- **Training or experience in laboratory animal medicine or in the use of the species at the institution:** Dr. Parbhoo earned his DVM from Texas A&M University May 2012. Dr. Parbhoo has provided relief veterinary services (locum) to Houston area clinics from May 2019 to now. Dr. Parbhoo worked as the Lead Veterinarian at The Vet Corner from January 2015 to January 2019, and is a USDA Category I Accredited Veterinarian since 2012.

Responsibilities: Dr. Parbhoo conducts weekly visits and is on call if the need arises. He will also be an alternate for the IACUC.

Time contributed to program: Part-time-0.2 FTE

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
 - a. At least once every six months, the IACUC uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare), as a basis for the review.
 - b. To facilitate the review, the IACUC will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The review will include, but not necessarily be limited to, a review of the following:
 - i. IACUC Membership and Functions;
 - ii. IACUC Records and Reporting Requirements;
 - iii. Husbandry and Veterinary Care (all aspects);

- iv. Personnel Qualifications (Experience and Training);
 - v. Occupational Health and Safety; and
 - vi. Emergency and Disaster Plans
- c. In addition, the institution's PHS Assurance will also be reviewed.
 - d. If program deficiencies are noted during the review, they will be categorized as significant or minor and the IACUC will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
 - e. Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.
 - f. Contingency plans are in place to allow for unexpected conditions. During these times, the IACUC will consider flexibilities in the conduct of official business. The IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing as per NIH Notice NOT-OD-06-052.
- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
- a. At least once every six months at least two members of the IACUC will visit all of the institution's facilities and any surgical areas where vertebrate animals are maintained for more than 12 hours. Areas also inspected may include holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals will also be inspected.
 - b. The IACUC uses the Guide and other pertinent resources, e.g., the PHS Policy, as a basis for the inspection. To facilitate the inspection, the IACUC will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
 - c. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the IACUC will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
 - d. Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded from participating in any portion of the inspections.
 - e. Contingency plans are in place to allow for unexpected conditions. During these times, the IACUC will consider flexibilities in the conduct of official business and semiannual animal facility inspections. The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities.
- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3., and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:
- The Inspection Team Leaders collect individual comments and concerns from their team members and prepare reports which are submitted to the IACUC Administrator who in-turn will draft the reports and make them available for the IACUC, using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.

- The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures, the reports will state so.
 - Departures from the Guide that are not compliant with PHS Policy, will be identified by the IACUC as noncompliance and will be reported to OLAW.
 - The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
 - The semiannual report to the IO will indicate that the TTUHSC El Paso animal facility is the only animal facility at present and it is AAALAC accredited.
 - The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
 - Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.
 - Continuing deficiencies will be tracked by the IACUC staff and be discussed as a standing report at monthly IACUC meetings for appropriate action until resolved.
 - In compliance with PHS Policy IV.B.3. and the American Association for Accreditation of Laboratory Animal Care (AAALAC), the IACUC files through the Institutional Official, at least annually, a certification to OLAW that the reviews and inspections have been conducted at the TTUHSC El Paso facility and reports any violations of guidelines or assurances which were observed and which have continued after notification of the Institution by the IACUC.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
- a. Any individual may report concerns to the IO or any member of the IACUC.
 - b. Notices are located in the animal facilities and laboratories advising individuals how and where to report animal welfare concerns.
 - c. Animal welfare concerns reported by individuals, in good faith, will include a mechanism for anonymity, compliance with applicable whistleblower policies, nondiscrimination against the concerned/reporting party, and protection from reprisals.
 - d. Reports of animal welfare concerns are kept anonymous to the extent possible and when requested, as per TTUHSC EP OP 52.03: "A Reporter may remain anonymous when reporting allegations of wrongdoing. However, certain reports may not be able to be investigated, or action by TTUHSC El Paso may be limited, unless the Reporter's identity is disclosed. Once a Reporter provides his/her identity, confidentiality cannot be guaranteed.
 - e. Reported concerns will be brought to the attention of the full IACUC. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.
 - f. The IACUC will report such actions to the IO and, as warranted, to OLAW. Reports to the IO may be made via meeting minutes, semiannual report of IACUC evaluations, or by separate letter. Reports to OLAW will be in writing and through the IO. Initial reports to both the IO and OLAW may be made verbally.
- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- a. Recommendations to the IO are discussed and developed by the IACUC.
 - b. The IACUC's recommendations are either included in the IACUC Meeting minutes, a report of the IACUC's evaluations, or by separate letter.
 - c. Such documents are reviewed and approved by the IACUC and then submitted to the IO.
- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:
- All new protocols are required to go through a consultation with the veterinarian, prior to submission for review.
 - Protocols are submitted via a web-based online system (Integrated Research Information System, iRIS) which assigns an identifying number.
 - The IACUC office screens the protocol for completeness.
 - New protocols are assigned to a pre-review team by the IACUC Chair or designee, which consists of, at a minimum, a primary reviewer (a scientist), and a secondary reviewer (the veterinarian). A nonscientist will be assigned as a tertiary reviewer. A safety services member is also assigned as part of the pre-review team to review any safety concerns. Any questions or concerns are relayed in writing to the principal investigator.
 - After the pre-review, the protocols are available to all IACUC members prior to and during convened IACUC meetings. Once responses are received from the investigator, the originally assigned review team presents the protocol to the full IACUC for review.
 - A member will not participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC. A member who has a conflicting interest also cannot contribute to the constitution of a quorum.
 - In regard to IACUC functions, all use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

Full-Committee Review

- All new protocols are required to go through a consultation with the veterinarian, prior to submission for review. Veterinarian consultation is highly recommended for Three-Year renewals.
- New protocols and Three-Year renewals are reviewed through full committee review (FCR). The agenda is available to all committee members. As described above, each protocol is assigned two or more reviewers.
- The IACUC uses FCR for new protocols, Three Year Renewal, and animal welfare related amendments. DMR is used for annual status report review. Expedited and/or special circumstances are handled via DMR. No other review processes are possible.
- IACUC meetings are primarily conducted in person. If the need arises, a video or telephone conference may be used.
- At a convened meeting with a quorum present, each protocol is presented by the primary reviewer and any outstanding issues are thoroughly discussed.

- Following the presentation and associated discussion, the primary reviewer presents a motion for either a) approval; b) modifications required to secure approval, or c) withhold approval.
- Following the primary reviewers motion, a vote is taken.
- A majority vote of the quorum at a convened meeting is needed for the motion to carry.
 - If modifications are required to secure approval, the committee will vote to send the response to the modifications of the protocol to DMR or FCR.
 - According to IACUC Policy #7, to which all members have agreed, when the outcome is to require modifications, the committee must unanimously vote to review the protocol via DMR once resubmitted.
 - Once approved through FCR or DMR, minor modifications such as typographical or arithmetic errors, misspellings, incorrect rooms, change in personnel (except PI), animal numbers less than 10% may be confirmed by IACUC administrative/support personnel.

Designated-Member Review

The IACUC uses designated member review in two ways:

- As requested by an investigator
- Subsequent to FCR

Requested by Investigator

- The PI shall submit an appropriately completed IACUC protocol form and a request for DMR through iRIS. The request must contain a justification for conducting a DMR.
- The IACUC staff will notify the IACUC Chair (or designee) of the request. The Chair will determine whether or not to approve DMR. The PI will only be notified if the DMR request is not approved.
- If the DMR request is approved by the chair, the Chair (or designee) will notify the IACUC staff to poll the IACUC members.
- Each IACUC member will have access to the item submitted for IACUC consideration, the request for DMR, and any other necessary information concerning the proposed research project for their consideration about a DMR. Each IACUC member will have an opportunity to approve the DMR or call for FCR.
- Records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after 72 hours and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting. The PI will only be notified if DMR will not occur.
- If FCR is requested by any committee member, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- If the results of the poll support the DMR, the Chair (or designee) will initiate the DMR process. At least one member of the IACUC who is qualified to conduct the review will be assigned by the Chair (or designee) to review the protocol and have the authority to approve, require modification to secure approval or request FCR prior to the previous approval's anniversary date.
- If more than one designated reviewer is assigned, their decisions must be unanimous. All reviewers receive access to the same documents, are able to review each other's comments, and must agree to all modifications.
- The possible outcomes of DMR are as follows:

- 1) Approval;
 - 2) Require modifications (to secure approval); and
 - 3) Referral for FCR.
- “Withhold approval” is not a possible outcome of DMR.

DMR for Annual Status Reports

- Annual Status Reports (ASRs) will be reviewed by DMR.
- One member of the IACUC will be assigned by the Chair (or designee) to review the ASR and have the authority to approve, recommend FCR, or require modification to secure approval prior to the previous approval’s anniversary date.
- All ASRs will be posted to an IACUC agenda and documented in the IACUC minutes. Additionally, all study documents will be available (in iRIS) for every IACUC member to review.

DMR in Special Circumstances

- While the TTUHSC El Paso IACUC prefers that protocol reviews be conducted at a full committee meeting, the IACUC may, during times of extended shut downs of the university under special situations, including pandemic, war and inclement weather, when the committee cannot make quorum, or other circumstances when FCR is impractical, switch to full DMR review of all protocols, at the discretion of the IACUC chair and all members of the committee after obtaining concurrence to use the DMR method. If FCR is requested, teleconference or video conferencing as per NIH Notice NOT-OD-06-052 will be conducted to establish a quorum.
- This review would occur according to the procedure specified for expedited review (above). FCR would commence on the normal schedule when the special circumstance has passed.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review [by FCR or DMR] of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the Institution's PHS Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure appropriate
 - d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and

- nonmedical care of the animals will be directed by a veterinarian.
 - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 - f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the investigator.
- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:
- Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III.D.6. above.
 - Examples of changes considered to be significant include, but are not limited to, changes:
 - a) from nonsurvival to survival surgery;
 - b) resulting in greater pain, distress, or degree of invasiveness;
 - c) in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
 - d) in species;
 - e) in study objectives;
 - f) in Principal Investigator (PI);
 - g) that impact personnel safety;
 - h) anesthesia, analgesia, sedation, or experimental substances;
 - i) euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals and
 - j) duration, frequency, type, or number of procedures performed on an animal.

¹Changes of less than 10% in the approximate number of animals used of mice of the genus *Mus*, rats of the genus *Rattus*, and USDA approved species that are bred for use in research are considered minor and administratively approved.

DMR for Simple Animal Strain Changes

- Animal strain changes that do not change the purpose of the study, or impact animal welfare, will be reviewed by DMR. Examples include changes between “wild-type” mouse or rat strains with a different genetic background (such as changing C57BL/6 to BALB/c), or the use of a different strain with the same gene knocked out.
- One member of the IACUC will be assigned by the Chair (or designee) to review the strain change amendment and have the authority to approve, recommend FCR, or require modification to secure approval.
- All strain change amendments will be posted to an IACUC agenda and documented in the IACUC minutes. Additionally, all study documents will be available (in iRIS) for every IACUC member to review.

Veterinary Verification Consultation

- In some instances, specific significant changes in approved research may be handled in consultation with the institutional veterinarian (IVET) authorized by the IACUC. This is called veterinary verification consultation (VVC).
- The IVET is not conducting DMR, but is serving as a subject matter expert to verify that the changes proposed are in compliance with the IACUC-reviewed and -approved policy and it is appropriate for the animals in this circumstance. Consultation with the IVET must be documented.
- The IVET may refer to the IACUC any request that does not meet the parameters of the IACUC-reviewed and -approved policies.
- Examples of changes that **can** be verified by VVC include:
 - a) Anesthesia, analgesia, or sedation, provided that animal welfare is not compromised;
 - b) Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;
 - c) Duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are already approved in the protocol.
- Examples of changes that **cannot** be verified by VVC include:
 - a) Change a surgery from a non-survival to a survival
 - b) Increase pain, distress, or degree of invasiveness
 - c) Change housing or use of animals to a non-LARC location
 - d) Change species
 - e) Change study objectives
 - f) Change Primary Investigator
 - g) Make changes that will impact personnel safety.
 - h) Add new procedures to a protocol.
- Consultation with the IVET will be documented through iRIS study correspondence by having the IVET verifying the change send the correspondence to the PI, IACUC Chair, and IACUC Research Compliance Specialist II through the protocol in iRIS.
- The PI must submit an amendment with revised protocol, through iRIS, within five business days of the consultation.
- The IACUC Research Compliance Specialist II will assign the protocol amendment to the IVET for review and approval.

8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

- a. Principal Investigators are notified through iRIS correspondence via the on-line system (iRIS).
- b. Principal Investigators will receive a list of stipulations via the iRIS system. The stipulations will state the identified issue and may suggest action for correction. PIs are expected to address and highlight changes for each stipulation in the revised protocol, and as necessary, add commentary in the stipulation response.
- c. Investigators are notified if approval is withheld (in writing via the iRIS system) with statements as to the reasons for the IACUC's decision and then provided an opportunity to respond in person or in writing.
- d. The IO has access to the iRIS system and can view the IACUC minutes and agendas as needed.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:
 - a. Post-Approval Monitoring - All animal health is monitored regularly after the approval of the protocol. Vivarium personnel are charged to monitor protocol compliance and to report any incidence of noncompliance. Vivarium personnel are able to access and review copies of approved protocols. In addition, the veterinarian may perform random audits for compliance with approved protocols. Non-compliance shall be reported to the IACUC chair and support staff. The IACUC chair will then call for a subcommittee to review and investigate the potential non-compliance according to internal SOP's.
 - b. USDA Covered Species – Protocols involving USDA covered species are reviewed by members of the IACUC annually by FCR or DMR using the same processes as outlined in III.D.6.
 - c. Non-USDA Covered Species – Protocols involving non-USDA covered species are reviewed by a member or members of the IACUC annually.
 - d. Annual protocol reviews are recorded in the IACUC meeting minutes.
 - e. The IACUC meeting minutes are reviewed by the IACUC.
 - f. Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6 above.

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:
 - a. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.
 - b. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
 - c. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the Institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation in writing to OLAW. Preliminary reports may be made verbally.
 - d. Suspensions, whether temporary or permanent, will be reported to OLAW in accordance with NIH Notice of February 24, 2005, NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals.

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:
 1. Control and Prevention Strategies

The Occupational Health and Safety program (OHSP) is designed to promote a safe work environment by minimizing the risk of illness or injury associated with working

with or around research animals and research-related hazards. The OHSP is administered by our Infectious Disease (ID) nurse. The ID nurse plans and monitors the program. The program covers all individuals who work with animals directly (students, faculty, and staff) as well as those who may be exposed (indirectly) to animals or their by-products in common areas or laboratories. An individual (Safety Services, Facilities, and Police Department) enrolls in the OHSP when requesting access to the LARC. Researchers are enrolled when their visit to the OHSP professional is complete and confirmed via email to the IACUC administrator.

2. Hazard Identification and Risk Assessment

The IACUC relies on the various safety committees within TTUHSC El Paso, including the Institutional Biosafety Committee (IBC) and Safety Services, to assess the dangers of procedures that use hazardous biologic, chemical or physical agents, including ionizing and non- ionizing radiation.

It is the IACUC's position that the PI is most capable of assessing the risk to themselves and their workers in their unique laboratory situation. Therefore, the IACUC recommends that the PI work in concert with the OHSP professional, IBC, Safety Services, and appropriate members of the LARC staff to provide necessary training to laboratory personnel.

The use of hazardous biological, chemical or physical agents must be approved by the appropriate safety committee, as appropriate prior to approval by the IACUC.

3. Facilities, Equipment and Monitoring

The animal facility was built in 2005 and added onto in 2011, and is a state of the art animal research complex equipped with various engineering and environmental controls to minimize exposure to harmful agents and hazardous activities. A commercial cage washer, vented dissection table, ventilated cage changing hoods, autoclaves, compressed gas racks, and changing/showering facilities are provided. The safety shower is present in the cage wash. The eyewash units are present in procedure rooms. Safety equipment is maintained and calibrated routinely.

4. Personal Hygiene

The LARC is equipped with two locker rooms with shower stalls. All personnel are required to maintain a high standard of personal cleanliness. Suitable protective prevention equipment for use in the animal facility and laboratories are supplied to the animal facilities staff. Facility dedicated scrubs and shoes are provided to LARC personnel, and there is a laundry facility within the LARC. Personnel are required to wash their hands and launder and change clothing to maintain personal hygiene. Lab coats or personal protective equipment worn in the animal facility are not to be worn outside of the animal facility. Personnel are not permitted to drink, use tobacco products, or apply cosmetics in animal rooms.

5. Animal Experimentation Involving Hazards

Potential hazards, such as animal bites, hazardous chemical or infectious agents, radioactive chemicals, chemical cleaning agents, allergens, and zoonotic diseases that are associated in dealing with animal use, are identified and evaluated. Health and safety specialists with knowledge in the appropriate disciplines are involved in the assessment of risks in conjunction with the development of the appropriate procedures for the management of those risks. Safety Services maintains written

policies and procedures governing the use of biohazards, toxic chemicals and physical hazards. These policies are enforced by means of facilities inspections and protocol review.

6. Personal Protection

Animal care personnel are required to wear the university supplied, appropriate personal protection. This protective equipment may include items such as masks and face shields, gloves, shoe covers, disposable gown, bonnet and scrub suits. Personnel are prohibited from wearing protective clothing and equipment outside the animal facility.

Research personnel are required to wear PPE appropriate to the biosafety level to which they are working, such as masks/respirators, disposable gowns, gloves, bonnets and shoe covers.

7. Medical Evaluation and Preventive Medicine for Personnel

- Risk Assessment Health Questionnaire for Animal Contact and Evaluations
 - All animal users are enrolled in the Occupational Health and Safety program. Users cannot opt-out of the program, but may decline Immunizations.
 - The Risk Assessment Health Questionnaire is used by the OHSP professional to gather starting information. Health histories are collected by the OHSP professional for evaluation and follow-up. Compliance with HIPAA regulations are maintained by direct action of the OHSP professional. Likewise, all medical records are maintained by the OHSP professional in HIPAA-compliant manner.
 - The Risk Assessment Health Questionnaire and Employee Health for Animal Users booklet are available on the IACUC website, in iRIS under the 'Help' section, and from the IACUC Administrator. All non-enrolled animal users and new research personnel must review and complete the forms. The employee schedules an appointment with the OHSP professional for evaluation of the completed Risk Assessment Health Questionnaire, who recommends and/or requires follow-up care.
 - The employee then completes the required actions or signs declination statement (i.e. declining immunizations, etc.).
 - The signed memorandum is retained with the OHSP professional in a HIPAA compliant manner.
 - On the 3 year anniversary of their enrollment, individuals still active in the Program will complete an updated Risk Assessment Health Questionnaire and submit it to the OHSP professional for additional evaluation/recommendations.
- Immunizations
 - Immunizations at TTUHSC El Paso are suggested, but not required. However, un-vaccinated personnel may be excluded from participation in studies. The decision for exclusion is risk-based and upon recommendation by OHSP and Safety Services.
 - Available vaccines are provided by OHSP personnel when indicated.
 - Examples of the immunizations provided to employees include tetanus, hepatitis B, MMR, influenza, etc.
 - All employees and students are required to obtain two initial TB tests.
- Precautions taken during pregnancy, illness or decreased immunocompetence.

- During the health history evaluation OHSP professional may identify those who are pregnant, or have illness/decrease immunocompetence. The OHSP professional will provide information and training pertinent to their individual situation.
- Personnel are advised that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals.
- If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/her health care professional, human resources, etc. Likewise, all personnel are advised to contact the OHSP professional should they experience any change in health status and require additional training.
- Personnel who are not involved with animal care and/or use, but need to enter areas when animals are housed or used are identified by the OHSP program
 - Personnel from the Physical Plant and Texas Tech Police personnel are given a tour of the facility including PPE available and PPE required in certain areas. Physical plant personnel who have exposure to vivarium ductwork and/or maintenance of HVAC filters may wear eye and respiratory protection and have additional training upon request.
 - Visitors that are authorized by the LARC Director to access the vivarium support areas are also required to sign-in/out. Any visitors are escorted by LARC staff or laboratory staff.
- Availability and procedures for treatment of bites, scratches, illness or injury.
 - In the event of injury or exposure, incidents are reported to the Supervisor and/or Manager.
 - First aid treatment is administered immediately at the patient location, and subsequent medical treatment is sought for serious injuries. The patient may then receive treatment by the OHSP professional in the Occupational Health office and/or University Medical Center (UMC) Emergency Room. The OHS and UMC are both within three blocks of TTUHSC El Paso.
 - Signage on procedures directing staff to the OHS or UMC are posted within the vivarium.
- Procedures/program for reporting and tracking injuries and illnesses.
 - Injuries are promptly reported to Human Resources and a "Workers Compensation First Report of Injury" form filed.
 - Personnel are instructed to report animal related injuries to the OHSP professional.
 - When seeking medical attention for an illness or injury, a complete description of exposure to animals is provided to medical personnel. Any spills or potential hazards are reported to Safety Services.

8. ABSL3

For working in the ABSL3, personnel are required to wear a PAPR with a shroud, a Tyvek, double booties, and double gloves. LARC personnel are issued scrubs and shoes that are dedicated to the ABSL3. There is the option to shower out.

All workers in the ABSL-3 facility undergo extensive training. Procedures and PPE requirements are exhaustively covered in a biosafety manual produced for this facility. Personnel are required to sign a consent form to work in this facility, undergo

yearly training with Safety Services, and obtain training as set forth by the IACUC and Vice President for Research.

The ABSL3 facility contains one room for animal housing with the Tecniplast Isocage (negative pressure) and Biosafety cabinets (Type II). The facility contains all necessary support equipment and spaces required for ABSL3 registration with USDA APHIS due to the nature of the agents used within the facility. The floors are broadcast epoxy and all floor drains are sealed. Air is HEPA-filtered in and out of the rooms. Air pressure in rooms is negative relative to adjacent halls, and halls within the ABSL3 facility are negative relative to the remainder of the animal facility. A pass-through autoclave is present in the facility for autoclaving biohazardous waste. A personnel locker room and shower are located at the entrance/exit of the ABSL3 facility. Access to the facility is granted by the Laboratory Manager, LARC Veterinarian, Biosafety Officer, and VP for Research.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

1) Training of LARC staff:

- The training of the LARC staff is the responsibility of the Attending Veterinarian.
- Classes are held on a regular basis for all animal caretakers. "Hands on" and "on-the-job" training sessions are held for all LARC personnel. Other training is provided as new standard operating procedures and forms are developed.
- The training programs employed are those made available to laboratory animal care technicians by the American Association for Laboratory Animal Science.
- The AALAS technician certification program is administered by the Attending Veterinarian.
- All LARC technicians complete the CITI modules entitled "Working with IACUC" and "Reducing Pain and Distress in Laboratory Mice and Rats" which outline the current laws and regulations, the ethics of animal experimentation, the responsibility of each person to ensure that animals receive humane treatment, the responsibilities and function of the IACUC and the 3 R's (Reduction, Refinement, and Replacement) of animal research.
- Each person then completes additional modules relevant to the species held within the LARC. All records of CITI training are maintained with CITI and in the online iRIS system.

2) Training of Laboratory Animal Investigators:

- The TTUHSC El Paso assurance is posted on the IACUC website along with all policies governing live animal use. Animal investigators are made aware of these items prior to their initial approval for animal work and reminded by inspection committees (along with policies to report animal neglect and abuse) at the semi-annual inspections.
- The IACUC-approved training process is initiated prior to or at the time of requesting an iRIS account. Training is also verified at the submission of a new protocol application/renewal (which must list all personnel to be involved with the animal work), or an amendment (adding personnel or adding a species to an existing approved protocol).

- The day-to-day operation and record keeping of the training requirements is administered by the LARC, IACUC staff, and/or available in iRIS.
- Records are checked to determine if the personnel have completed the necessary training. For those not compliant with required training, the item under review (initial application/renewal/amendment) will not be approved until all training is complete.
- Once the item is approved personnel are then authorized to use the animals and gain access to the LARC facility.
- The training program has two major elements:
 - The first is a series of online modules which specifically address the training topic requirements currently listed in 9 CFR, Part 2, Subpart C, Section 2.32(c).
 - We currently use an online series offered by the Collaborative Institutional Training Initiative (CITI). Individuals working with animals in laboratories complete a series of modules relating to their proposed use of animals.
 - All animal investigators must complete the modules entitled "Working with IACUC" and "Reducing Pain and Distress in Laboratory Mice and Rats" which outline the current laws and regulations, the ethics of animal experimentation, the responsibility of each person to ensure that animals receive humane treatment, the responsibilities and function of the IACUC and the 3 R's (Reduction, Refinement, and Replacement) of animal research.
 - Each person then completes modules relevant to the species and procedures which they are using which outlines the principles of husbandry and demonstrating basic experimental procedures entitled "Working with (Species) in Research Settings Course (species will vary i.e. mice, rats, ferrets, fish, etc.)."
 - Each person also completes modules related to Conflict of Interest in Research.
 - In addition, as applicable, research personnel working with antibodies or conducting surgery must complete modules entitled Antibody Production in Animals and Aseptic Surgery.
 - All records of CITI training are maintained with CITI and in the online iRIS system.
 - In addition to the training described above, individuals using new species or employing new techniques are provided one-on-one instruction and assistance from the LARC veterinary staff. Training is generally provided in the form of workshops (anesthesia, euthanasia and survival surgery workshops) on at least a semi-annual basis.
- Records of participation in training exercises initiated by the LARC are kept by the LARC.

3) Personnel Training

Training is required for all personnel associated with approved protocols. Safety Services administers introductory safety training following its Chemical Hygiene plan.

CITI (Collaborative Institutional Training Initiative) training, titled "Working with the IACUC," "Reducing Pain and Distress in Laboratory Mice and Rats," and "Working with (Species) in Research Settings (Species will vary, i.e. mice, rats, ferrets, fish) are required. Additional training in Antibody Production in Animals and Aseptic Surgery may also be required, as applicable. Training regarding financial conflicts of interest

in research is also required and completed through CITI, along with the submission of an annual research financial disclosure form through iRIS.

Procedural and task-specific training is provided to individuals by their lab supervisors. Additional training needs for PIs and research personnel, including students, is determined by the Attending Veterinarian and the IACUC during protocol review. The LARC also has training requirements before access is granted to the facility. Each person must complete a LARC Orientation as well as a Bioprotection course. The Orientation covers navigating within the facility, as well as expectations, and where to obtain help. The Bioprotection course discusses what Bioprotection is, why it is necessary, and the roles that research personnel and the LARC have in keeping pathogens out of the LARC.

For the ABSL2 space, research personnel must attend a LARC Orientation that is specific for the ABSL2, which covers safety and expectations of working in the ABSL2. There is an ABSL2 refresher course that is required on an annual basis.

For the ABSL3 space, research and LARC personnel are required to attend an ABSL3 Safety Orientation, read the ABSL3 manual, and attend the mandatory annual refresher training course. This is monitored by Safety Services and the Office of Research.

Additional training needs are also identified during introductory safety training. Training can be conducted by experienced persons listed on the protocol, the Attending Veterinarian, other faculty, or outside experts as is indicated. If requested the Veterinary staff can also provide species and biomethodology training. Animal-specific training is provided to the animal technicians by expert researchers as necessary. Training on zoonotic diseases and animal allergens are provided upon enrollment in the OHSP.

4) Training of IACUC Members:

- Each IACUC member is provided with an electronic copy (hard copies provided if requested by the member) of the following:
 - The PHS Policy for the Humane Care and Use of Laboratory Animals;
 - The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
 - The ARENA/OLAW IACUC Guidebook;
 - The AVMA Guidelines on Euthanasia;
 - A copy of this Assurance.
- All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the CITI website, www.citiprogram.org. Courses include "Working with the IACUC" and "Essentials for IACUC members". Specific training related to the Chair or Community Member will also be completed by those in the specific roles.
- Training regarding financial conflicts of interest in research is also required and completed through CITI, along with the submission of an annual financial disclosure through iRIS.
- Continuing education will be available; IACUC members will complete refresher training at least once every three years. The training is identical to the initial training.
- Members must also obtain OHSP clearance, as described above.
- Current CV's are maintained in iRIS.

- New members will submit their curriculum vitae and will also receive orientation to the program by the IACUC Chair (or designee) at the time they are assigned to the IACUC. This includes orientation to the program, ensuring all personnel receive the documents above, discussion and questions from the new member and ensuring that the new member understands and completes the CITI program training.
- Continuing education is also provided at meetings or as separate training sessions, when requested.
- Documentation of training will be maintained for at least three (3) years.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

A. This Institution will maintain for at least 3 years:

1. A copy of this Assurance and any modifications made to it, as approved by the PHS
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Deborah Clegg PhD, Vice President for Research.
5. Records of accrediting body determinations

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

A. The Institutional reporting period is the fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW by December 1 of each year. The annual report will include:


1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
3. Any change in the IACUC membership
4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities), and submitted the evaluations to the Institutional Official, Deborah Clegg, PhD, Vice President for Research
5. Any minority views filed by members of the IACUC

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy
2. Any serious deviations from the provisions of the Guide
3. Any suspension of an activity by the IACUC

C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Deborah Clegg, PhD	
Title: Vice President for Research	
Name of Institution: Texas Tech University Health Sciences Center at El Paso	
Mailing Address: 5001 El Paso Drive MS 31001 El Paso, Texas 79905	
Physical Address: 137 Rick Francis MSB II, Room 5A105 El Paso, Texas 79905	
Phone: 915-215-4545	Fax: 915-783-5223
E-mail: dclegg@ttuhsc.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 04/11/2023

B. PHS Approving Official (to be completed by OLAW)	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD 20892-6910 Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

VIII. Membership of the IACUC

Date: 03/27/2023			
Name of Institution: Texas Tech University Health Sciences Center at El Paso			
Assurance Number: D19-01056			
IACUC Chairperson			
Name*: Munmun Chattopadhyay			
Title*: Associate Professor			Degree/Credentials*: PhD
Address*: 5001 El Paso Drive El Paso, Texas 79905			
E-mail*: munmun.chattopadhyay@ttuhsc.edu			
Phone*: 915-215-4170			Fax*: 915-783-5223
IACUC Roster			
Member Code**	Degree/Credentials	Position Title***	PHS Policy Membership Requirements****
2/Violeta Salais	DVM	Attending Veterinarian/LARC	Veterinarian/Scientist
3	PhD	Managing Director/ Librarian	Non-Scientist
4	PhD	Professor/ Infectious Disease	Scientist
5	PhD	Assistant Professor/Medical Education	Scientist
6 Wendilywn Walker	PhD	Assistant Professor/ Infectious Disease	Scientist/Vice Chair
7	PhD	Assistant Professor/Cancer	Scientist
8	PhD	Assistant Professor/ Cancer	Scientist
9	MS	Unit Manager/Safety Services	Scientist
10	MSN	Nurse Practitioner	Non-Affiliated
11	MA	Senior Director/Safety Services	Non-Voting/Safety Consultant
12	BMS	Senior Director/Office of Research	Non-Voting
13/Pratish J. Parbhoo	DVM	Back-up Veterinarian/ LARC	Scientist/Alternate for #2

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not “community member” or “retired”).

**** PHS Policy Membership Requirements:

Veterinarian	Veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
Scientist	Practicing scientist experienced in research involving animals.
Nonscientist	Member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
Nonaffiliated	Individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: Myrna Arvizo, BMS	
Title: Senior Director	
Phone: 915-215-4162	E-mail: myrna.arvizo@ttuhsc.edu

X. Facility and Species Inventory

[illegible]

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.